

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ARB/P/83/WO	FOR FURTHER ACTION <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</small>	
International application No. PCT/GB 00/ 03328	International filing date (day/month/year) 31/08/2000	(Earliest) Priority Date (day/month/year) 31/08/1999
Applicant BRADFORD PARTICLE DESIGN PLC et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.
☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

T/GB 00/03328

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 852 140 A (NISSAN CHEMICAL IND LTD) 8 July 1998 (1998-07-08) column 1, line 5 - line 12 page 11 -page 12; examples 1-7 ---	1-6, 10-16, 23,31
X	WO 96 31202 A (ELAN CORP PLC) 10 October 1996 (1996-10-10) page 3, line 13 - line 16 page 7 -page 8; example 1 ---	1-5,23, 31
X	EP 0 582 169 A (BAYER ITALIA SPA) 9 February 1994 (1994-02-09) page 3; example 1 ---	1-5,23, 31
X	WO 92 11000 A (SANOL ARZNEI SCHWARZ GMBH) 9 July 1992 (1992-07-09) page 6 -page 7; examples 1,2 ---	1-5,23, 31
-/-		

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *I* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *A* document member of the same patent family

Date of the actual completion of the international search

22 February 2001

Date of mailing of the international search report

02/03/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Boulois, D

INTERNATIONAL SEARCH REPORT

International Application No

T/GB 00/03328

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 13136 A (MICROENCAPSULATION CENTRE ;RICHARD JOEL (FR); BENOIT JEAN PIERRE () 2 April 1998 (1998-04-02) page 1, line 4 - line 28 page 5, line 5 -page 7, line 18 page 12 -page 13; example 9 ---	1-5,23, 31
X	WO 99 25322 A (CARLI FABIO ;COLOMBO ITALO (IT); ALESSI PAOLO (IT); CORTESI ANGELO) 27 May 1999 (1999-05-27) page 4 -page 5; examples 1,6 ---	1-5,23, 31
X	WO 97 31691 A (UNIV KANSAS ;SUBRAMANIAM BALA (US); SAID SAID (US); RAJEWSKI ROGER) 4 September 1997 (1997-09-04) page 1, line 16 - line 26 page 15 -page 23; examples 1-4 ---	1-5,23, 31
X	WO 95 01221 A (UNIV BRADFORD ;HANNA MAZEN (GB); YORK PETER (GB)) 12 January 1995 (1995-01-12) cited in the application page 37 -page 50; examples 5,10,16 ---	1-5,23, 31
X	DEBENEDETTI P G ET AL: "APPLICATION OF SUPERCRITICAL FLUIDS FOR THE PRODUCTION OF SUSTAINED DELIVERY DEVICES" JOURNAL OF CONTROLLED RELEASE,NL,ELSEVIER SCIENCE PUBLISHERS B.V. AMSTERDAM, vol. 24, no. 1 / 03, 1 May 1993 (1993-05-01), pages 27-44, XP000363918 ISSN: 0168-3659 the whole document ---	1-5,23, 31
P,X	WILKINS S. ET AL: "The formation of indomethacin:polymer co-precipitates by the solution enhanced dispersion by supercritical fluids (SEDS) process" J. OF PHARMACY AND PHARMACOLOGY, vol. 51, September 1999 (1999-09), page 291 XP000905174 the whole document ---	1-6, 10-31
X	TAYLOR L. ET AL: "Spectroscopic characterization of interactions between PVP and indomethacin in amorphous molecular dispersions" PHARM. RES., vol. 14, 1997, pages 1691-1698, XP000905065 page 1691 -page 1692 page 1695 --- -/-	1-6, 10-23,31

INTERNATIONAL SEARCH REPORT

International Application No

T/GB 00/03328

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SHEKUNOV B. ET AL: "Control of Particle Morphology using solution enhanced dispersion by supercritical fluids (SEDS)" PHARM. RES., vol. 14, 1997, pages 195-196, XP000905093 the whole document	1
E	WO 01 03821 A (YORK PETER ;BRADFORD PARTICLE DESIGN PLC (GB); HANNA MAZEN HERMIZ) 18 January 2001 (2001-01-18) page 8, line 14 - line 21 page 22 -page 23; example 3	1-6, 10-23,31
X	US 4 404 183 A (KAWATA HIROITSU ET AL) 13 September 1983 (1983-09-13) claims 1,2	1-6, 10-16, 23,31
A	WO 97 44028 A (MERCK FROSST CANADA INC ;HANCOCK BRUNO (CA); WINTERS CONRAD (CA);) 27 November 1997 (1997-11-27) the whole document	7,8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

/GB 00/03328

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0852140 A	08-07-1998	AU 702088 B	11-02-1999
		AU 6669396 A	12-03-1997
		NO 980549 A	02-04-1998
		NZ 315089 A	29-06-1999
		CA 2228907 A	27-02-1997
		CN 1192677 A	09-09-1998
		CZ 9800326 A	17-06-1998
		WO 9706781 A	27-02-1997
WO 9631202 A	10-10-1996	IE 950233 A	16-10-1996
		AU 700612 B	07-01-1999
		AU 5286696 A	23-10-1996
		CA 2217462 A	10-10-1996
		EP 0818996 A	21-01-1998
		JP 11503147 T	23-03-1999
		NZ 304975 A	24-09-1998
		US 5641745 A	24-06-1997
		ZA 9602670 A	09-10-1996
EP 0582169 A	09-02-1994	IT 1255792 B	16-11-1995
		CA 2101680 A	06-02-1994
		JP 7002700 A	06-01-1995
		US 5491154 A	13-02-1996
		US 5622978 A	22-04-1997
WO 9211000 A	09-07-1992	DE 4041563 A	25-06-1992
		AT 116542 T	15-01-1995
		CA 2098814 A	23-06-1992
		DE 59104172 D	16-02-1995
		DK 563176 T	06-03-1995
		EP 0563176 A	06-10-1993
		ES 2067324 T	16-03-1995
		FI 932761 A	16-06-1993
		GR 3015623 T	30-06-1995
		HU 217817 B	28-04-2000
		IE 914313 A	01-07-1992
		JP 6504531 T	26-05-1994
		KR 162105 B	01-12-1998
		PT 99892 A,B	31-12-1992
		US 5424076 A	13-06-1995
WO 9813136 A	02-04-1998	FR 2753639 A	27-03-1998
		AT 194926 T	15-08-2000
		DE 69702666 D	31-08-2000
		EP 0930936 A	28-07-1999
		ES 2149613 T	01-11-2000
		PT 930936 T	29-12-2000
WO 9925322 A	27-05-1999	IT 1296464 B	25-06-1999
		AU 2153199 A	07-06-1999
		BR 9814656 A	03-10-2000
		EP 1033977 A	13-09-2000
WO 9731691 A	04-09-1997	US 5874029 A	23-02-1999
		US 5833891 A	10-11-1998
		AU 709384 B	26-08-1999
		AU 2193697 A	16-09-1997
		CA 2247900 A	04-09-1997

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

EP/GB 00/03328

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9731691 A		EP 0885038 A	23-12-1998
WO 9501221 A	12-01-1995	AT 174530 T	15-01-1999
		AU 677345 B	17-04-1997
		AU 7007194 A	24-01-1995
		CA 2166301 A	12-01-1995
		DE 69415320 D	28-01-1999
		DE 69415320 T	24-06-1999
		DK 706421 T	23-08-1999
		EP 0706421 A	17-04-1996
		ES 2128564 T	16-05-1999
		GR 3029612 T	30-06-1999
		JP 8511987 T	17-12-1996
		NZ 267697 A	26-05-1997
		SG 47392 A	17-04-1998
		US 5851453 A	22-12-1998
WO 0103821 A	18-01-2001	NONE	
US 4404183 A	13-09-1983	JP 1272484 C	11-07-1985
		JP 56133217 A	19-10-1981
		JP 59048810 B	29-11-1984
		JP 1591530 C	30-11-1990
		JP 2009007 B	28-02-1990
		JP 56049314 A	02-05-1981
		CA 1146866 A	24-05-1983
		CH 648484 A	29-03-1985
		DE 3024858 A	22-01-1981
		ES 493152 D	16-11-1981
		ES 8200557 A	01-02-1982
		ES 499854 D	01-06-1982
		ES 8205125 A	16-09-1982
		FR 2460667 A	30-01-1981
		FR 2489146 A	05-03-1982
		GB 2053681 A, B	11-02-1981
		IT 1132169 B	25-06-1986
		SE 448342 B	16-02-1987
		SE 8004938 A	06-01-1981
		US 4343789 A	10-08-1982
		US 4673564 A	16-06-1987
WO 9744028 A	27-11-1997	AU 3004997 A	09-12-1997
		BG 103000 A	30-09-1999
		BR 9709097 A	03-08-1999
		CZ 9803738 A	16-06-1999
		EP 0910368 A	28-04-1999
		HR 970262 A	30-06-1998
		JP 11512754 T	02-11-1999
		NO 985342 A	16-11-1998
		PL 329940 A	26-04-1999
		SK 156798 A	18-01-2000
		TR 9802345 T	22-03-1999
		US 6063811 A	16-05-2000

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 19 June 2001 (19.06.01)	Applicant's or agent's file reference ARB/P/83/WO
International application No. PCT/GB00/03328	Priority date (day/month/year) 31 August 1999 (31.08.99)
International filing date (day/month/year) 31 August 2000 (31.08.00)	
Applicant YORK, Peter et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 26 March 2001 (26.03.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Zakaria EL KHODARY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

BREWSTER, Andrea, Ruth
Greaves Brewster
24A Woodborough Road
Winscombe
North Somerset BS25 1AD
ROYAUME-UNI

Date of mailing (day/month/year) 27 October 2001 (27.10.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference ARB/P/83/WO	
International application No. PCT/GB00/03328	
International filing date (day/month/year) 31 August 2000 (31.08.00)	

1. The following indications appeared on record concerning:

☒ the applicant
 ☐ the inventor
 ☐ the agent
 ☐ the common representative

Name and Address

BRADFORD PARTICLE DESIGN PLC
Unit 69 Listerhills Science Park
Campus Road
Bradford BD7 1HR
United Kingdom

State of Nationality

GB

State of Residence

GB

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☒ the name
 ☐ the address
 ☐ the nationality
 ☐ the residence

Name and Address

BRADFORD PARTICLE DESIGN LIMITED
Unit 69 Listerhills Science Park
Campus Road
Bradford BD7 1HR
United Kingdom

State of Nationality

GB

State of Residence

GB

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☒ the International Preliminary Examining Authority

☐ the designated Offices concerned
☒ the elected Offices concerned
☐ other:
The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35


Authorized officer

R. Raissi

Telephone No.: (41-22) 338.83.38

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference ARB/P/83/WO		FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)
International application No. PCT/GB00/03328		International filing date (day/month/year) 31/08/2000	Priority date (day/month/year) 31/08/1999	
International Patent Classification (IPC) or national classification and IPC A61K9/00				
Applicant BRADFORD PARTICLE DESIGN PLC et al.				
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>				
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input checked="" type="checkbox"/> Certain documents cited</p> <p>VII <input checked="" type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>				
Date of submission of the demand 26/03/2001		Date of completion of this report 13.11.2001		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized officer Boulois, D Telephone No. +31 70 340 3878		



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03328

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-37, A1-A13, 38, as originally filed
39

Claims, No.:

1-31 as originally filed

Drawings, sheets:

1/21-21/21 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03328

- ☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:
see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 7-9,17-20,29,30
	No:	Claims 1-6,10-16,21-28,31
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-31
Industrial applicability (IA)	Yes:	Claims 1-31
	No:	Claims

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03328

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03328

R Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: EP-A-852140
D2: WO-A-9631202
D3: EP-A-582169
D4: WO-A-9211000
D5: WO-A-9813136
D6: WO-A-9925322
D7: WO-A-9731691
D8: WO-A-9501221 (cited in the application)
D9: J. Controlled Release, 24(1993), 27-44
D10: Pharm. Res., 14(12),1691-8
D11: US-A-4404183

2. The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of Claims 1-6,10-16,21-28,31 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

For the judgement of novelty of the present application, it appeared that the concepts of "coformulation" and "stable" must be interpreted widely and not only in the light of the explanations given in the description. It appears moreover that the term "stable" has not a very clear definition in the present application, even with the explanations given on page 3, lines 1-9, since it is impossible to know which percentages are meant.

It was also considered that any "coformulation" obtained by a process allowing the formulation of a drug in amorphous drug, would fulfill the stability requirements of the claims..

Lack of novelty of the following claims is stated against the disclosure of the following documents:

- lack of novelty of claims 1-6,10-16,23,31 over D1 (see D1, col. 1, l. 5-12; page 11-12, examples 1-7)
- lack of novelty of claims 1-5,23,31 over D2 (see D2, p. 3, l. 13-16; p. 7,8, example 1)

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03328

- lack of novelty of claims 1-5,23,31 over D3 (see D3, page 3, example 1)
- lack of novelty of claims 1-5,23,31 over D4 (see D4, pages 5-7, examples 1,2)
- lack of novelty of claims 1-5,23,31 over D5 (see D5, p. 1, l. 4-28; p. 5, l. 5-p. 7, l. 18; p.12-13, example 9)
- lack of novelty of claims 1-5,23,31 over D6 (see D6, p. 4,5, examples 1,6)
- lack of novelty of claims 1-5,23,31 over D7 (see D7, p. 1, l. 16-26; p. 15-23, examples 1-4)
- lack of novelty of claims 1-5,23,31 over D8 (see D8, p. 37-50, examples 5,10,16)
- lack of novelty of claims 1-5,23,31 over D9
- lack of novelty of claims 2-6, 10-16, 21-28, 31 over D10 (see D10, p. 1691,2,5)
- lack of novelty of claims 1-6,10-16,23,31 over D11 (see D11, claims 1,2)

3. The documents D1, D2, D3, D4, D5,D6,D7,D8,D9,D10,D11 appear to be of particular relevance as far as inventive step is concerned (Article 33(3) PCT). These documents solve indeed the same problem, namely making a coformulation of an active in amorphous state, so that, as far as novel subject-matter is concerned, the present application does apparently not fulfill the requirements of Article 33(3) PCT over these prior art documents.

It seems in particular to be a normal design option to use the same concept for a specific drug.

It also pointed out that the introduction of a disclaimer in an independent claim does not restore the inventive step of the said claim.

Therefore, as no unexpected effect for the present composition (as far as novel) over the prior art compositions has been demonstrated, this composition does apparently not fulfill the requirements of Article 33(3) PCT.

Re Item VI

Certain documents cited

Certain published documents (Rule 70.10)

Application No
Patent No

Publication date(day/month/year)

Filing date(day/month/year)

Priority date (day/month/year)

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03328

WO-A-0103821(E1) 18.1.2001

7.7.2000

7.7.1999

Non-written disclosures (Rule 70.9)

Kind of non-written disclosure Date of non-written disclosure(day/month/year) Date of written disclosure(day/month/year)

J. of Pharm. Pharmacol.,51,sept. 1999,291 (E2)

sept. 1999

The document E1 will be taken in consideration in the regional phase for the judgement of novelty of claims 1-6,10-23,31 (see E1, page 8, l. 14-21; p. 22-23, example 3).
The content of document E2 may also be relevant for the novelty of claims 1-6,10-31 (see the whole document.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1,D2,D3,D4,D5,D6,D7,D9,D10 and D11 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

1. It is clear from the description that the process of preparation of claim 26 is essential to the definition of the invention.

Since independent claims 1,2 10, 17 do not contain this feature they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

2. The present application does not meet the requirements of Article 6 PCT because claims 24,25 and 27 are not clear.

It appears from the description on page 1, lines 6-12 that the SEDS process exists in modified versions, and therefore that the term does not have a precise and recognized

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meaning.

3. The term "COX-2 selective inhibitor" as used in the present dependent claims 7 and 8 defines the active agent by its pharmacological profile, namely its affinity to a enzyme.

However, a compound cannot be sufficiently characterised by its pharmacological profile or its mode of action as it is done by an expression like "COX-2 selective inhibitor" because it is difficult to know which substances are encompassed in this expression. **Moreover, the definition of an "inhibitor" is also not clear.**

For instance it is highly credible that sulfuric acid or sodium hydroxide would also be "COX-2 selective inhibitor". It is also not clear at which level of affinity a compound can be defined as an inhibitor (or as an agonist). A lot of compounds have indeed both activities depending on the concentration used.

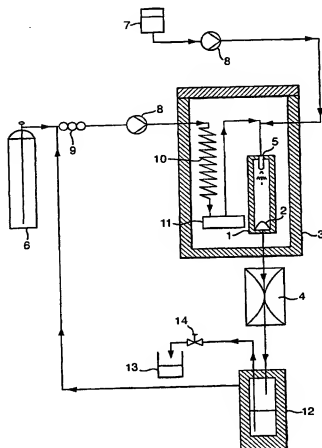
Thus the present dependent claims 7 and 8 are not clear, because the pharmacological definition is vague and renders thus the scope of said claims obscure (Article 6 PCT).

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[Continued on next page](54) Title: **COFORMULATION METHODS AND THEIR PRODUCTS**

(57) Abstract: A coformulation of an active (preferably pharmaceutically active, for instance a COX-2 enzyme inhibitor) substance and an oligomeric or polymeric excipient, containing at least 10 % of the active, between 80 and 100 % of which is amorphous. The amorphous phase is stable, with respect to the crystalline phase(s), for at least three months after its preparation when stored at between 0 and 10 °C. The invention also provides processes, preferably involving SEDS™ particle formation, for preparing such a coformulation.

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NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
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B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 92 11000 A (SANOL ARZNEI SCHWARZ GMBH) 9 July 1992 (1992-07-09) page 6 -page 7; examples 1,2	1-5,23, 31

-/-

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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